Exhibit 188
(Filed Under Seal)

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE NAMENDA DIRECT PURCHASER ANTITRUST LITIGATION	15 Civ. 7488 (CM)(JCF) 17 MC 0274 (CM)(JCF) 17 MC 0314 (CM)(JCF)
	MEMORANDUM AND ORDER

JAMES C. FRANCIS IV
UNITED STATES MAGISTRATE JUDGE

In this putative class action asserting violations of antitrust law by defendants Actavis plc (now known as Allergan plc) and Forest Laboratories, LLC (together, "Forest") in connection with its patented Alzheimer's drugs Namenda IR and Namenda XR (brand names for memantine hydrochloride), the Direct Purchaser Class Plaintiffs (the "plaintiffs") have filed a motion to compel non-party Lupin Pharmaceuticals, Inc. ("Lupin Pharmaceuticals") to produce documents responsive to a subpoena. In addition, Lupin Pharmaceuticals has filed a motion to quash a deposition subpoena served upon it by Forest.[1] The motion to compel is granted; the motion to quash is granted in part and denied in part.

[1] The plaintiffs' motion to compel was originally filed in the United States District Court for the Eastern District of Pennsylvania. It was transferred to this Court on July 26, 2017. (Docket Entry dated July 26, 2017, In re Namenda Direct Purchaser Antitrust Litigation, No. 17 MC 274 (S.D.N.Y.)). Lupin Pharmaceuticals' motion to quash was originally filed in the United

Background

A. Substantive Claims

I have outlined the allegations in this litigation in numerous prior opinions. See In re Namenda Direct Purchaser Antitrust Litigation, No. 15 Civ. 7488, 2017 WL 3314233, at *1 (S.D.N.Y. Aug. 2, 2017); In re Namenda Direct Purchaser Antitrust Litigation, No. 15 Civ. 7488, 2017 WL 3085342, at *1-2 (S.D.N.Y. July 20, 2017); In re Namenda Direct Purchaser Antitrust Litigation, No. 15 Civ. 7488. 2017 WL 2693713, at *1-2 (S.D.N.Y. June 21, 2017); In re Namenda Direct Purchaser Antitrust Litigation, No. 15 Civ. 7488, 2017 WL 2226591, at *1-2 (S.D.N.Y. May 19, 2017). The asserted collusive settlement scheme is particularly relevant to this dispute.

Specifically, the plaintiffs allege that in late 2007 Lupin Pharmaceuticals submitted an Abbreviated New Drug Application ("ANDA") to the FDA seeking approval to market a generic version of Namenda IR prior to the expiration of the relevant patent, known as the '703 Patent.[2] (Memorandum of Law In Support of Direct

States District Court for the District of Columbia, and was transferred to this Court on August 18, 2017 (Docket Entry dated Aug. 18, 2017, In re Namenda Direct Purchaser Antitrust Litigation, No. 17 MC 314 (S.D.N.Y.)). I heard oral argument on both motions on August 28, 2017.

[2] The entity that actually filed the ANDA was Lupin Pharmaceuticals' parent company, Lupin Limited. (Transcript of

Purchaser Class Plaintiffs' Motion to Compel Third Party Lupin Pharmaceuticals, Inc. to Produce Documents Responsive to Plaintiffs' Rule 45 Subpoena ("Pl. MTC Memo.") at 6). In response, Forest filed a patent infringement action against Lupin Pharmaceuticals in January 2008. (Pl. MTC Memo. at 6). Forest and Lupin Pharmaceuticals settled that action in December 2009. (Pl. MTC Memo. at 6). As part of that settlement, Lupin Pharmaceuticals agreed not to launch its generic version of Namenda IR until July 11, 2015, absent certain contingencies. (Pl MTC Memo. at 6). Lupin Pharmaceuticals received final approval of its generic drug on April 10, 2015. (Pl. MTC Memo. at 7). However, by the time it was able to begin marketing its medication pursuant to the settlement agreement, Forest had engineered a "product hop" using a "hard switch" strategy that "succeeded in converting a substantial portion of the market to its new product, Namenda XR," a drug that is pharmacologically identical to Namenda IR but not therapeutically equivalent to the older drug under FDA regulations. (Pl. MTC Memo. at 7); In re Namenda, 2017 WL 2693713, at *1.

B. Subpoenas

The plaintiffs served a subpoena on Lupin Pharmaceuticals on

Oral Argument dated Aug. 28, 2017 ("Tr.") at 17).

January 9, 2017. (Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action dated Jan. 5, 2017 ("Document Subpoena"), attached as Exh. A to Declaration of Daniel C. Simons dated July 19, 2017 ("Simons Decl."), at 2). The Document Subpoena defined its target to include Lupin Pharmaceuticals' parent corporation. (Schedule A to Document Subpoena at 1). It sought documents in Lupin Pharmaceutical's "possession, custody and/or control" -- defined as including material in the possession of "any affiliated company from which [Lupin Pharmaceuticals] ha[s] the practical ability to obtain documents without service of legal process" (Schedule A to Document Subpoena, at 2) -- and included a request for "[a]ll documents regarding the scale-up, validation, manufacturing, and/or marketing of Generic Namenda. By way of example only, this would include, but not be limited to, agendas and minutes of meetings of any teams, committees, or departments involved in the aforementioned activities; and communications with third-party ingredient suppliers" (Schedule A to Document Subpoena at 5 ("Request No. 4")). Pursuant to Rule 45 of the Federal Rules of Civil Procedure, which requires the target of the subpoena to object "before the earlier of the time specified for compliance or 14 days after the subpoena is served," objections were due on January 23, 2017. Fed. R. Civ. P. 45(d)(2)(B).

On February 22, 2017, counsel for Lupin Pharmaceuticals contacted plaintiffs' counsel to schedule a time to meet and confer on the scope of the Document Subpoena. (Declaration of Zarema A. Jaramillo dated Aug. 2, 2017 ("Jaramillo 8/2/17 Decl."), ¶ 2). The first conference call regarding the Document Subpoena took place on March 1, 2017. (Jaramillo 8/2/17 Decl., ¶ 3). On March 9, 2017, Lupin Pharmaceuticals served its responses to the Document Subpoena, which included objections stating that, "to the extent that [the Document Subpoena] improperly purport[s] to seek information from distinct corporate entities . . . not controlled by Lupin Pharmaceuticals, Inc.[,] Lupin will respond on behalf of Lupin Pharmaceuticals, Inc. only." (Lupin Pharmaceuticals, Inc.'s Response and Objections to Direct Purchaser Plaintiffs' Subpoena to Produce Documents, Information, or Objects or to Permit Inspection of Premises in a Civil Action dated March 9, 2017, attached as Exh. G to Simons Decl., at 2-3). In a letter April 28, 2017, plaintiffs' counsel informed Lupin Pharmaceuticals that its objections were untimely. (Letter of Daniel C. Simons dated April 28, 2017, attached as Exh. B to Simons Decl., at 2 n.1).

The plaintiffs and Lupin Pharmaceuticals continued to confer about the scope of the Document Subpoena, including Request No. 4. (Pl. MTC Memo. at 8; Jaramillo 8/2/17 Decl., ¶¶ 5-9). During that process, the plaintiffs suggested that, in response to Request No.

4, Lupin Pharmaceuticals produce "'high-level' documents related to [its] plans to launch generic Namenda IR." (Jaramillo 8/2/17 Decl., ¶ 5). After a conference with Lupin Pharmaceuticals employees, counsel for the company informed the plaintiffs that "the employees most likely to have such documents would be members of [Lupin Pharmaceutical's] Generics Department (internally referred to as 'Commercial')." (Jaramillo 8/2/17 Decl., ¶ 6). Lupin Pharmaceuticals ultimately agreed to produce "high level documents sufficient to show Lupin's plans to scale-up, manufacture, and/or market Namenda IR that are prepared by Lupin's Commercial Department." (Letter of Zarema Jaramillo, dated May 5, 2017, attached as Exh. C to Simons Decl., at 2; Jaramillo 8/2/17 Decl., ¶¶ 6, 8-9).

At the beginning of July 2017, immediately after Lupin Pharmaceuticals completed production pursuant to the agreement, the plaintiffs objected that responsive documents were missing, specifically, documents sufficient to show the following:

(1) when Lupin Pharmaceuticals began preparations for real world launch of its generic Namenda product;

(2) when or where validation batches were made;

(3) when the first commercial batches were manufactured;

(4) when the commercial batches needed for launch were fully manufactured;

(5) the quantity Lupin Pharmaceuticals estimated it would have to produce for launch; and

(6) communications from project managers concerning preparation for launch, launch meetings, or spreadsheets tracking what batches were manufactured.

(Pl. MTC Memo. at 9; Jaramillo 8/2/17 Decl., ¶¶ 11-13).[3] On July 25, 2017, while attempting to resolve this dispute, the plaintiffs asked Lupin Pharmaceuticals if its response to Request No. 4 "related to documents from Lupin in both the United States and India." (Email of Daniel Simons dated July 25, 2017, attached as part of Exh. C to Jaramillo 8/2/17 Decl.). Lupin Pharmaceuticals answered that only the U.S. entity was "relevant," making explicit, apparently for the first time, that Lupin Pharmaceuticals had not requested responsive documents from its Indian parent company, Lupin Limited. (Emails of Zarema Jaramillo and Daniel Simons dated July 26, 2017, attached as part of Exh. C to Jaramillo 8/2/17 Decl.).

[3] Lupin Pharmaceuticals identifies another category of documents purportedly sought by the plaintiffs: documents sufficient to show "the status of [active pharmaceutical ingredient ("API")] manufacturing in preparation for launch" (Non-Party Lupin Pharmaceuticals, Inc.'s Memorandum of Law in Opposition to Direct Purchaser Plaintiffs' Motion to Compel Production of Documents ("Lupin MTC Memo.") at 6, 10; Email of Daniel Simons dated July 21, 2017, attached as Exh. B to Jaramillo 8/2/17 Decl.). Although the plaintiffs do not specifically list this category in their opening brief, such documents appear to be encompassed within the categories the plaintiffs seek.

Meanwhile, on February 3, 2017, Forest had served a subpoena for documents on Lupin Pharmaceuticals. (Declaration of Zarema A. Jaramillo dated July 10, 2017 ("Jaramillo 7/10/17 Decl."), ¶ 4). Forest and Lupin Pharmaceuticals came to the same agreement regarding document production as had Lupin Pharmaceuticals and the plaintiffs. (Jaramillo 7/10/17 Decl., ¶ 5). Forest then served a deposition subpoena on Lupin Pharmaceuticals seeking testimony on eighteen topics. (Subpoena to Testify at a Deposition in a Civil Action dated April 25, 2017 ("Deposition Subpoena"), attached as part of Exh. A to Jaramillo 7/10/17 Decl.). The parties then negotiated as to the scope of the subpoena. (Jaramillo 7/10/17 Declaration, ¶¶ 7-18; Declaration of Kristen O'Shaughnessy dated July 24, 2017 ("O'Shaughnessy Decl."), ¶¶ 7-17). Forest whittled down the topics covered by the Deposition Subpoena to nine:

(1) Sales projections and actual sales for Generic Namenda IR;

(2) Forecasts regarding anticipated regulatory approval dates, launch dates, and price of any Generic IR, including assumptions used;

(3) The company's understanding and evaluation of whether Namenda IR or the '703 Patent was subject to a pediatric exclusivity period;

(4) The expected timeline for patent litigation arising from the ANDA for Generic Namenda IR, and fees and costs incurred or expected to be incurred in connection with such litigation;

(5) The actual, proposed, or contemplated plans for "at-risk" launch of any Generic Namenda IR and past instances of "at-risk" launch of any generic product;[4]

(6) The purpose or effect of any proposed or actual agreements to settle the patent litigation arising from the ANDA for Generic Namenda IR, including the negotiations of such agreements;

(7) Any communication between Lupin Pharmaceuticals and any other parties who filed an ANDA for Generic Namenda IR and who were sued in connection with such an ANDA filing, concerning competition with or market entry of Generic Namenda and concerning the settlement of patent litigation concerning Namenda;

(8) The authenticity and circumstances surrounding the creation of the documents and the company's practices in regards to the creation of such documents that Lupin Pharmaceuticals produces to any party in this litigation;

(9) The steps the company took to comply with the Deposition Subpoena.

(Email of Kristin O'Shaughnessy dated July 1, 2017, attached as Exh. D to Jaramillo 7/10/17 Decl.; Memorandum of Points and Authorities in Support of Non-Party Lupin Pharmaceuticals, Inc.'s Motion to Quash Subpoena to Testify at a Deposition in a Civil Action ("Lupin MTQ Memo.") at 5-6). However, they were ultimately

[4] "'At risk' entry refers to circumstances in which a generic has received final approval from the FDA to market its product but the infringement litigation is continuing and therefore the generic may be 'at risk' of incurring infringement damages if it enters the market but loses the patent litigation." (First Amended Class Action Complaint ("Compl."), ¶ 9 n.7).

unable to agree upon its scope. (Jaramillo 7/10/17 Decl., ¶ 19; O'Shaugnessy Decl., ¶ 18).

Discussion

A. Legal Standards

"A two-step analytical framework governs a motion to compel discovery. First, the moving party must demonstrate that the information sought is discoverable, including, among other things, that it is relevant. Second, '[o]nce relevance has been shown, it is up to the responding party to justify curtailing discovery.'" Johnson v. J. Walter Thompson U.S.A., LLC, No. 16 Civ. 1805, 2017 WL 3055098, at *2 (S.D.N.Y. July 18, 2017) (citations omitted) (alteration in original) (quoting Allison v. Clos-ette Too, LLC, No. 14 Civ. 1618, 2015 WL 136102, at *8 (S.D.N.Y. Jan. 9, 2015)). Relevant information is discoverable if it is "proportional to the needs of the case," taking into account factors such as "whether the burden or expense of the proposed discovery outweighs its likely benefit." Fed. R. Civ. P. 26(b)(1). To determine whether a document subpoena imposes an undue burden, a court should examine "such factors as relevance, the need of the party for the documents, the breadth of the document request, the time period covered by it, the particularity with which the documents are described[,] and the burden imposed." MacNamara v. City of New York, No. 04 Civ. 9612, 2006 WL 3298911, at *15 (S.D.N.Y. Nov. 13,

2006) (quoting Travelers Indemnity Co. v. Metropolitan Life Insurance Co., 228 F.R.D. 111, 113 (D. Conn. 2005)). Similarly, in determining "whether to allow a third-party deposition over the deponent's objection," a court must "balance the interests served by demanding compliance with the subpoena against the interests furthered by quashing it," considering "whether the information is necessary and whether it is available from any other source." Anwar v. Fairfield Greenwich Ltd., 297 F.R.D. 223, 226 (S.D.N.Y. 2013) (quoting Aristocrat Leisure Ltd. v. Deutsche Bank Trust Co. Americas, 262 F.R.D. 293, 299 (S.D.N.Y. 2009)).

Litigants and courts are instructed to be especially solicitous of non-party targets of subpoenas. See, e.g., Fed. R. Civ. P. 45(d)(1); MacNamara, 2006 WL 3298911, at *15. However, "[b]ecause the burden is on the party seeking to quash a subpoena, that party cannot merely assert that compliance with the subpoena would be burdensome without setting forth the manner and extent of the burden and the probable negative consequences of insisting on compliance." Aristocrat Leisure, 262 F.R.D. at 299 (quoting Kirschner v. Klemons, No. 99 Civ. 4828, 2005 WL 1214330, at *3 (S.D.N.Y. May 19, 2005)); see also, e.g., Wells Fargo Bank v. Konover, No. 3:05 CV 1924, 2009 WL 585430, at *6 (D. Conn. March 4, 2009); Jones v. Hirschfeld, 219 F.R.D. 71, 74-75 (S.D.N.Y. 2003). "Inconvenience alone will not justify an order to quash a

subpoena that seeks potentially relevant testimony." Aristocrat Leisure, 262 F.R.D. at 300 (quoting Kirschner, 2005 WL 1214330, at *2).

B. Analysis

1. Motion to Compel

Lupin Pharmaceuticals appears to concede that the information sought is relevant. Nevertheless, it argues that it has abided by its agreement with the plaintiffs to produce documents; that any additional documents it has would be low-level, ministerial documents "tangential to the documents already produced" such that the burden of searching for and producing them outweighs the plaintiffs' need; and that it is not obligated to produce any additional responsive documents that might be held by its parent company in India, Lupin Limited. (Lupin MTC Memo. at 3).

As noted, the agreement required Lupin Pharmaceuticals to produce "high level documents sufficient to show Lupin's plans to scale-up, manufacture, and/or market Namenda IR that were prepared by Lupin's Commercial Department." To the extent that Lupin Pharmaceuticals argues that the categories of documents the plaintiffs have identified are "outside of the [a]greement" (Lupin MTC Memo. at 10), I reject that contention. Those categories appear relevant to the company's preparation to launch its generic memantine product, and Lupin Pharmaceuticals has not provided any

evidence that they were excluded from the agreement's coverage. The fact that the plaintiffs did not specifically name those categories when providing examples of the documents it sought (Reply Brief in Further Support of Direct Purchaser Class Plaintiffs' Motion to Compel Third Party Lupin Pharmaceuticals, Inc. to Produce Documents Responsive to Plaintiffs' Rule 45 Subpoena ("Pl. MTC Reply") at 6 & n.10; Jaramillo 8/2/17 Decl., ¶ 5) is immaterial.

The plaintiffs complain that Lupin Pharmaceuticals restricted the definition of "high level documents" to documents "shared with the board or management team that discussed Lupin's plans and efforts to market generic Namenda IR." (Pl. MTC Memo. at 3 (quoting Letter of Zarema Jaramillo dated July 7, 2017, attached as Exh. I to Simons Decl., at 2)). However, they acknowledge that the production itself does not reflect this limitation. (Pl. MTC Memo. at 3 n.4). And the company asserts that, applying the plaintiffs' broader definition of high-level documents -- which would presumably include "summary documents, reports, [compilations], or records of meetings of Lupin's scale-up, validation, manufacture, and/or marketing efforts and abilities" (Pl. MTC Reply at 7) -- it "has satisfied its obligation." (Lupin MTC Memo. at 8-9).

Lupin Pharmaceuticals focuses on its promise to produce

documents "sufficient to show" its efforts to launch the generic drug, asserting that it produced documents "including forecasts, launch calendars, and ANDA-related filings." (Lupin MTC Memo. at 10). But according to the plaintiffs, the production is devoid of documents showing

> (1) the date process validation began, (2) the date process validation ended (and whether the first attempt at process validation was successful), (3) the date Lupin ordered API in preparation for launch, (4) the date Lupin received its API, (5) the date Lupin began manufacturing scale-up batches in advance of its July 11, 2015 launch, (6) the date Lupin completed manufacture of scale-up batches, (7) how many commercial batches (and what was the batch size) Lupin had successfully manufactured prior to July 11, 2015, and (8) whether Lupin experienced any difficulty in manufacturing scale-up batches.

(Pl. MTC Reply at 3). Again, these facts would seem to be included within the agreement; indeed, they are integral to a meaningful understanding of the company's efforts to launch the product. Moreover, the plaintiffs indicate that six other non-party generic drug producers have produced documents reflecting facts like these in response to subpoenas identical to the subpoena served on Lupin Pharmaceuticals. (Pl. MTC Reply at 5). It thus appears that the company has not yet produced documents "sufficient to show" its launch plans.

Lupin Pharmaceuticals next argues that searching for and producing further documents from its own files would be unduly

burdensome. (Lupin MTC Memo. at 11-14). But the showing is anemic, gaining what strength it has from the assertion that any additional documents produced would be "tangential." (Lupin MTC Memo. at 3, 11). That claim is unconvincing in light of the discussion above. And, as the plaintiffs point out, the company has failed to support its burden argument by, for example, "detailing the volume of documents at issue or the number of personnel hours that would be necessary to produce the [requested] documents." (Pl. MTC Memo. at 13).

Moreover, any argument that producing additional documents would be unduly burdensome is undermined by Lupin Pharmaceuticals' repeated assertions that it has no such documents. (Lupin MTC Memo. at 8 ("[Lupin Pharmaceuticals] informed [the] [p]laintiffs that the only high level launch-related documents responsive to [the] additional requests had already been produced."), 11 ("To the extent [the] [p]laintiffs are trying to compel [Lupin Pharmaceuticals] to produce additional high level documents [applying the plaintiffs' broader definition of 'high level'] . . . there is nothing to compel."), 13 ("[Lupin Pharmaceuticals] does not have additional documents to supplement its production . . . . The documents it produced are the documents on which it based the product launch.")). That, it turns out, is the key issue here: the documents the plaintiffs seek, "if [they] exist,

[] are located at [Lupin Pharmaceuticals'] corporate parent in India." (Lupin MTC Memo. at 13; Tr. at 16).

As permitted by Rule 45, the subpoena at issue requires Lupin Pharmaceuticals to produce documents within its "possession, custody, or control." Fed. R. Civ. P. 45(a)(1)(A)(iii); see also Chevron Corp. v. Salazar, 275 F.R.D. 437, 447 (S.D.N.Y. 2011). "'Control' is construed broadly to encompass documents that the respondent has 'the legal right, authority, or practical ability to obtain . . . upon demand.'" Chevron, 275 F.R.D. at 447 (alteration in original) (quoting Dietrich v. Bauer, No. 95 Civ. 7051, 2000 WL 1171132, at *3 (S.D.N.Y. Aug. 16, 2000), and collecting cases)). A domestic corporation has been found to have control over documents held by its foreign parent or subsidiary

> in circumstances where the relationship is such that the domestic corporation can "obtain documents from its foreign parent to assist itself in litigation;" where the domestic corporation can "easily obtain" documents from its parent when it has an interest in doing so; where documents ordinarily flow freely between them; or where the domestic corporation has the practical ability to obtain the requested documents for use in its business.

Doe Run Peru S.R.L. v. Trafigura AG, No. 3:11 MC 77, 2011 WL 13059042, at *2 (D. Conn. Aug. 24, 2011). "The burden of demonstrating that the party from whom discovery is sought has the practical ability to obtain the documents at issue lies with the party seeking discovery." Tiffany (NJ) LLC v. Qi Andrew, 276

F.R.D. 143, 148 (S.D.N.Y. 2011).

Lupin Pharmaceuticals relies first on its objections to the Document Subpoena limiting its responses to information actually possessed by Lupin Pharmaceuticals. Although I choose not to deem those objections waived even though they were untimely, see, e.g., Nimkoff Rosenfeld & Schechter, LLP v. RKO Properties, Ltd., No. 07 Civ. 7983, 2016 WL 3042733, at *4 (S.D.N.Y. May 24, 2016), they do not absolve Lupin Pharmaceuticals of the responsibility to produce documents in its "possession, custody, or control" as those terms are defined in the cases interpreting Rule 45. That is, notwithstanding any objection, Lupin Pharmaceuticals must produce documents from Lupin Limited if it can. Thus, neither Lupin Pharmaceuticals' objections nor its assertion that it would respond only "on behalf of Lupin Pharmaceuticals, Inc.," put the plaintiffs "on notice" of the company's position that it did not have the ability to obtain documents from Lupin Limited and that, therefore, the plaintiffs "would not be receiving any documents" from the parent company. (Lupin MTC Memo. at 15). The situation was exacerbated by the later representation that the material the plaintiffs sought would be in the possession of Lupin Pharmaceuticals' Commercial Department. (Jaramilla 8/2/17 Decl., ¶ 6). In light of these facts, Lupin Pharmaceuticals' failure to inform the plaintiffs until July 2017 of its position that it did

not have control of responsive documents housed with Lupin Limited is troubling, especially as fact discovery closes on September 15, 2017. (Order dated July 17, 2017).

Generally, a subpoena's proponent must establish that the target has the practical ability to obtain the requested records. Here, the plaintiffs' showing is not robust. The mere fact that Lupin Pharmaceuticals is a wholly-owned subsidiary of Lupin Limited is not sufficient. See, e.g., In re Vivendi Universal, S.A. Securities Litigation, No. 02 Civ. 5571, 2009 WL 8588405, at *3 (S.D.N.Y. July 10, 2009). Nor, in the absence of a showing of actual control, is it sufficient that that the parent and subsidiary have interlocking officers and directors (Pl. MTC Reply at 10); see In re Vivendi, 2009 WL 8588405, at *3 -- a characterization of corporate leadership that Lupin Pharmaceuticals denies, in any event (Tr. at 22).

The plaintiffs next argue that the information they seek must be kept and made accessible to the FDA pursuant to federal law, citing 21 C.F.R. § 314.150(b)(1), 21 U.S.C. § 355(k)(2), and 21 U.S.C. § 374(a)(1)(B). (Pl. MTC Reply at 5 & nn. 8-9, 9; Tr. at 7). Lupin Pharmaceuticals does not quarrel with that representation. However, the company argues that Lupin Limited, as the entity that submitted the ANDA, is responsible for keeping and producing these records upon the FDA's request. (Tr. at 17-

18, 32). Both 21 U.S.C. § 355(k) and 21 C.F.R. § 314.150(b)(1) are clearly directed to "the applicant." Section 355(k)(1) in part requires "the applicant" to maintain certain records "[i]n the case of any drug for which approval of an . . . [ANDA] is in effect." 21 U.S.C. § (k)(1). Subsection (k)(2) mandates that "[e]very person required under this section to maintain records" permit inspection of those records. 21 U.S.C. § (k)(2). The regulation allows the FDA to begin proceedings to withdraw approval of an ANDA if "the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain required records or to make required reports . . . , or [if] the applicant has refused to permit access to, or copying or verification of, its records." 21 C.F.R. § 314.150(b)(1).

On the other hand, 21 U.S.C. § 374(a)(1)(B) does not apply only to the applicant for approval of a drug. Rather, it covers "any factory, warehouse, establishment, or consulting laboratory in which prescription drugs . . . are manufactured, processed, packed, or held." 21 U.S.C. § 374(a)(1)(B). However, it allows inspection merely of "all things therein" relating to certain topics. 21 U.S.C. § 374(a)(1)(B). That is, that subsection does not appear to require those premises to have on hand any particular records, but only that the records that are located on-site may be

inspected. The plaintiffs' argument thus does not establish Lupin Pharmaceuticals' control of the requested information.

Nevertheless, at oral argument, counsel for Lupin Pharmaceuticals stated that "to the extent that [Lupin Pharmaceuticals] does need a document from Lupin, Ltd., . . . a process [] would need to take place to obtain those documents." (Tr. at 19). The process, although "not as simple as picking up the phone" or accessing a shared IT system (Tr. at 14, 18), does not appear onerous. Rather, Lupin Pharmaceuticals must contact Lupin Limited to identify which department and custodians are likely to have responsive documents and then arrange a search. (Tr. at 18-19). Lupin Pharmaceuticals' argument thus does not seem to be that Lupin Limited's documents are not within its control, but rather that providing them will involve some burden. And although counsel offered that Lupin Limited might "possibly" decline to produce information, she also stated that the parent regularly produces documents when it is itself the target of a subpoena. (Tr. at 19). In any case, from counsel's description of this "process," it is clear that the subsidiary has the practical ability to obtain documents from its parent corporation. Lupin Pharmaceuticals shall therefore produce the requested documents.

2. Motion to Quash

Here, again, Lupin Pharmaceuticals appears to concede the relevance of the most of information sought, except as to Lupin Pharmaceuticals' plans for an "at-risk" launch of generic Namenda IR or other generic drugs (Topic 5) and communications between Lupin Pharmaceuticals and other companies who sought to introduce generic memantine during the relevant time period (Topic 7). (Lupin MTQ Memo. at 10, 13-14). The company's primary argument is that Forest's proposed topics impose an undue burden because Forest has not demonstrated a need for the information. (Lupin MTQ Memo. at 8-14).

a. Relevance

i. Topic 5

This topic seeks information about plans for an "at-risk" launch of generic Namenda IR, as well as of other generic drugs. Lupin notes that it received final approval for generic Namenda IR "long after the settlement of the patent litigation, meaning that, by definition, Lupin could not have launched 'at risk.' Therefore, this topic has no relevance vis-à-vis Lupin." (Lupin MTQ Reply at 3-4). But that does not mean that Lupin Pharmaceuticals did not formulate plans in advance of final FDA approval. Insofar as it did, this is an appropriate topic for deposition. However, I agree that Forest has failed to explain

why the "at-risk" launch of non-Namenda generics is relevant here, and to that extent the topic is overbroad.

ii. Topic 7

Lupin Pharmaceuticals contends that information about communications among generic companies is not probative because the "overarching conspiracy claim" alleged in the operative complaint has been dismissed. (Lupin MTQ Memo. at 10). The company explains that the plaintiffs "allege a rimless hub-and-spoke conspiracy" in which "[t]here are no allegations that Lupin entered into agreements with the other generic companies regarding Namenda IR." (Lupin MTQ Reply at 4 n.3).

The operative complaint identifies Lupin Pharmaceuticals as one of eleven "Potential First-Filing Generics" -- that is, a generic manufacturer that could potentially enjoy a period during which it had the exclusive right to market generic memantine pursuant to federal law. (Compl., ¶¶ 7, 42). The complaint further asserts that the Potential First-Filing Generics had an incentive to "agree[] to delay launch [of generic memantine] in exchange for the elimination of any theoretical patent risk, but only if all other generics collectively did the same." (Compl., ¶¶ 58, 60). Count 4 and Count 5 allege an "overall conspiracy between and among [Forest] and the Potential First Filing Generics not to compete with each other." (Compl., ¶¶ 261, 270).

To be sure, in her decision on Forest's motion to dismiss, the Honorable Colleen McMahon, Chief Judge, excised the plaintiffs' allegations of "an overarching scheme to unlawfully maintain [Forest's] monopoly in the market for memantine hydrochloride." Sergeants Benevolent Association Health & Welfare Fund v. Actavis, PLC, Nos. 15 Civ. 6549, 15 Civ. 7488, 2016 WL 4992690, at *16 (S.D.N.Y. Sept. 13, 2016). But it appears that she was limiting Count 2, not Counts 4 or 5. See id. at *7 (describing Count 2 as "a claim against Forest for the unlawful maintenance of monopoly power under Section 2 of the Sherman Act 'through an overarching scheme to prevent [or] delay generic competition'").[5] Moreover, the claim was limited because it was "duplicative" of the plaintiffs' "claims related to the product hop and the settlement agreements." Id. I do not read the decision to indicate that allegations of agreements between and among Forest and the generic drug manufacturers are no longer a part of the operative complaint. Nor, indeed, does Forest, which filed one of the motions to dismiss that resulted in Judge

[5] In limiting this claim, the opinion cites page 40 of the plaintiffs' opposition to Forest's motion to dismiss. Id. at *16. That page, in turn, cites the paragraphs of the operative complaint comprising Count 2. ([Corrected*] Direct Purchaser Plaintiffs' Memorandum in Opposition to Defendants Forest and Merz's Motion to Dismiss Indirect Purchaser Plaintiffs' Class Action Complaint and Direct Purchaser Plaintiffs' First Amended Class Action Complaint at 40 (citing Compl., ¶¶ 244-250), ECF No. 69).

McMahon's opinion. (Forest's Memorandum of Points and Authorities in Opposition to Lupin Pharmaceuticals, Inc.'s Motion to Quash Subpoena to Testify at a Deposition in a Civil Action ("Def. MTQ Memo.") at 8-9).

b. Undue Burden

As with Lupin Pharmaceuticals' burden argument in response to the plaintiffs' motion to compel, its argument here is unsupported. As noted above, claims of burden must explain the manner and extent of the burden, as well as the consequences of compliance. See Aristocrat Leisure, 262 F.R.D. at 299. Lupin Pharmaceuticals has not done so. Indeed, the company merely states (albeit repeatedly) that complying with the Deposition Subpoena would require it to prepare and produce multiple high-level executives as witnesses, taking them away from their duties for several days. (Lupin MTQ Memo. at 2, 4, 15; Lupin MTQ Reply at 6). Lupin Pharmaceuticals has not identified how many witnesses would need to testify, or what would be involved in preparing them, other than voicing general complaints about "lengthy internal reviews and investigations of documents." (Letter of Zarema Jaramillo dated June 26, 2017, attached as Exh. C to Jaramillo 7/10/17 Decl., at 3). This is not surprising as, remarkably, counsel for Lupin Pharmaceuticals has refused even to broach the subject of burdensomeness with their client. (O'Shaugnessy Decl., ¶ 10;

Email of Kristen O'Shaugnessy dated June 22, 2017 ("O'Shaugnessy June 22 Email"), attached as Exh. 2 to O'Shaugnessy Decl.).

Lupin Pharmaceuticals' real argument appears to be that any burden is undue because the information sought can be gleaned from documents or declarations.[6] According to the company, the documents it has produced already provide sufficient information regarding topics 1-4 (sales projections and actual sales; forecasts for approval, launch, and price; Namenda IR's entitlement to pediatric exclusivity; timeline and costs of patent litigation) and 6 (purpose and effect of the settlement agreement with Forest, including negotiations). Lupin Pharmaceuticals offers declarations in lieu of testimony in response to Topics 5 (plans for an "at-risk" launch), 8 (authenticity of documents provided in response to document subpoenas), and 9 (steps taken to comply with the Deposition Subpoena).

Forest's argument regarding the first group of topics boils down to an insistence that it does not need to choose between a

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[6] Lupin Pharmaceuticals also objects to the second, third, and fourth topics to the extent that they seek testimony about a counterfactual world in which the alleged anticompetitive conduct alleged in the complaint did not occur, arguing that such hypotheses must come from an expert witness rather than a lay witness. (Lupin MTQ Memo. at 9). But those topics, as written, "merely require Lupin to testify about [its] own forecasts, projections, and expectations regarding its generic memantine product." (Def. MTQ Memo. at 13).

document subpoena and a deposition subpoena. (Def. MTQ Memo. at 12). That is true, as far as it goes. See Alexander v. F.B.I., 192 F.R.D. 37, 40 (D.D.C. 2000) (Rule 45 does not "present[] an 'either/or' option with respect to requests for documents or deposition"). However, the party issuing a subpoena must still avoid imposing undue burdens or expenses on the respondent. Fed. R. Civ. P. 45(d)(1). Forest argues that "the centrality of the Lupin Settlement Agreement to [the plaintiffs'] allegations" make it necessary "to obtain testimony from Lupin regarding the Lupin Settlement Agreement and the documents Lupin has produced." (Def. MTQ Memo. at 12). At oral argument, counsel for Forest fleshed out the kinds of information that it would seek at a deposition, noting, as I have above, that the documents Lupin Pharmaceuticals have produced do not appear to "tell[] the entire story" of the company's plans for launching a generic memantine product. (Tr. at 43). Moreover, because Lupin Pharmaceuticals has failed to establish with any specificity the burden which compliance with the Deposition Subpoena will impose, I will not quash the subpoena as to these topics.[7]

[7] Lupin Pharmaceuticals' argument that Topic 6 is particularly objectionable because "the settlement agreement expressly sets forth its purpose and effect" and because testimony about the settlement agreement would likely call for information protected by attorney-client privilege or work product immunity (Lupin MTQ Memo. at 13; Lupin MTQ Reply at 4) fails. See Universitas

As to the utility of a series of declarations instead of deposition testimony, Forest notes that declarations "do[] not meet Forest's discovery needs because [they] are not admissible testimony that can be used at trial." (O'Shaugnessy Decl., ¶ 7-9; O'Shaughnessy June 22 Email; Def. MTQ Memo. at 12). In light of Lupin Pharmaceuticals' insufficient showing of burden, I will not quash the subpoena on this ground.[8]

3. Cost-Shifting

"Cost-shifting is particularly appropriate in the context of subpoenas, since Rule 45 directs courts to minimize the burden on non-parties." US Bank N.A. v. PHL Variable Insurance Co., No. 12 Civ. 6811, 2012 WL 5395249, at *4 (S.D.N.Y. Nov. 5, 2012). "The factors to be considered in determining whether cost-shifting is

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Education, LLC v. Nova Group, Inc., No. 11 Civ. 1590, 2013 WL 57892, at *3 (S.D.N.Y. Jan. 4, 2013) (denying motion to quash based on "preemptive assertion" of privilege because "unadorned assertion that 'other questions [counsel] may ask may very well be protected from discovery by the attorney-client privilege'" does not satisfy standard for assertion of privilege under Rule 45); DR Systems, Inc. v. Eastman Kodak Co., No. 08 MC 6029, 2009 WL 1009839, at *3 (W.D.N.Y. April 14, 2009) (requiring non-party to produce witness to testify about documents produced because "[d]ocuments do not speak for themselves").

[8] To the extent that Forest is concerned about admissibility, I urge it to continue to confer with Lupin Pharmaceuticals to resolve this issue and thereby further limit the topics upon which the company need be deposed. (O'Shaugnessy June 22, Email (noting that Lupin Pharmaceuticals has proposed "a declaration in conjunction with an agreement that a Lupin witness would testify at trial to provide admissible evidence").

warranted include '(1) whether the nonparty has an interest in the outcome of the case; (2) whether the nonparty can more readily bear the costs; and (3) whether the litigation is of public importance.'" Id. (quoting In re World Trade Center Disaster Site Litigation, No. 21 MC 100, 2010 WL 3582921, at *1 (S.D.N.Y. Sept. 14, 2010). Although the operative complaint in this action includes allegations against Lupin Pharmaceuticals, the company is a non-party here as well as in the related litigation brought by indirect purchasers of Namenda. Moreover, there is no indication that Lupin Pharmaceuticals is in a better position to pay the costs of document production than are the plaintiffs, or the costs of deposition than is Forest. Therefore, the plaintiffs shall pay the reasonable costs of complying with the Document Subpoena. Likewise, if Forest seeks to go forward with a deposition on its noticed topics, it shall pay Lupin Pharmaceuticals' reasonable expenses incurred in complying with the Deposition Subpoena.

Conclusion

For the foregoing reasons, the plaintiffs' motion to compel (Case no. 17 MC 0274) is granted. Lupin Pharmaceuticals shall produce the requested documents within its possession, custody, or control on or before September 15, 2017. Lupin Pharmaceuticals' motion to quash (Case no. 17 MC 0314) is granted in part and denied in part. Lupin Pharmaceuticals shall produce one or more

deponents to testify on the identified topics (as limited above). The plaintiffs shall pay Lupin Pharmaceuticals' reasonable attorneys' fees and expenses incurred in complying with the Document Subpoena; Forest shall pay those expenses incurred in complying with the Deposition Subpoena.

SO ORDERED.

JAMES C. FRANCIS IV
UNITED STATES MAGISTRATE JUDGE

Dated: New York, New York
August 30, 2017

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